DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 19, 2014

Pinghu Sama Medical Packing Co., Ltd.
% Mr. Charles Shen
Regulatory Correspondent
MANTON BUSINESS AND TECHNOLOGY SERVICES
853 Dorchester Ln, Unit-b
New Milford, New Jersey 07646

Re: K141998
Trade/Device Name: SAMA Disposable Blood Pressure Cuff Barriers
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: July 23, 2014
Received: July 25, 2014

Dear Mr. Charles Shen,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

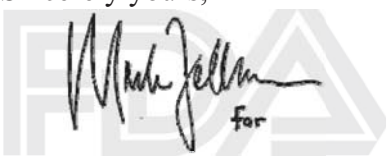
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number (if known): N/A

Device Name: SAMA Disposable Blood Pressure Cuff Barriers

Indications for Use:

This device has the potential to reduce or prevent patient to patient cross contamination which can occur during blood pressure measurement procedures, for single patient use only. It covers a blood pressure cuff to provide a barrier between patient and cuff.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

5.1 Submitter & Foreign Manufacture Identification

Pinghu Sama Medical Packing Co., Ltd.
1 Qunfeng Road, South of Lindai
Pinghu, Zhejiang Province, China 314202
Tel: (086) 573-85923333
Submitter's FDA Registration Number：N/A

5.2 Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester LN, Unit-B
New Milford, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

5.3 Date of Summary: July 15, 2014

5.4 Device Name:

Proprietary Name:	SAMA Disposable Blood Pressure Cuff Barriers
Common Name:	Blood Pressure Cuff Cover
Classification Name:	Blood Pressure Cuff
Device Classification:	II
Regulation Number:	21 CFR 870.1120
Panel: General	Cardiovascular
Product Code:	DXQ

5.5 Predicate Device Information:

(1) K031195, "Cuf-Cover", manufactured by "Ethox Corp", Located in Buffalo, NY, USA

5.6 Device description:

This device is a cover for blood pressure cuffs. It is made of soft medical grade paper with a polyethylene coating. Blood pressure cuffs are used throughout the healthcare industry as a means of monitoring patient blood pressure. Because blood pressure cuffs

are used on multiple patients there is a concern about cross contamination. When the blood pressure cuffs become contaminated they should be cleaned. A blood pressure cuff barrier can reduce the need to clean blood pressure cuffs.

In order to address the cross contamination issue for blood pressure cuffs a blood pressure cuff barrier has been designed. The product is a non-sterile, clean, ready to use sleeve that is applied between the patient arm and the blood pressure cuff. The cuff barrier has the potential to reduce transfer of patient contamination to the cuff and from the cuff to the patient.

The blood pressure cuff barrier is a single use product designed to survive average use during an average hospital stay. If the blood pressure cuff cover becomes contaminated, soiled or torn during this time it would be replaced with a new blood pressure cuff barrier.

The blood cuff barrier has a two layer structure. The inner layer that has immediate contact with patient skin is made of soft medical grade paper. The outer layer that has immediate contact underneath the blood pressure cuff is made of cast film of polyethylene.

The whole barrier is approximately 20 μm thick and is available in various different length and width. The barrier can be secured around the patient arm by two sided adhesive tape with removable liner. The adhesive tape and liner are located at the end of outer layer and do not contact the patient skin.

5.7 Intended Use:

This device has the potential to reduce or prevent patient to patient cross contamination which can occur during blood pressure measurement procedures, for single patient use only. It covers a blood pressure cuff to provide a barrier between patient and cuff.

5.8 Summary of Device Testing:

Bench testing was performed per ISO 10993-1, and internal procedures to ensure that the SAMA Disposable Blood Pressure Cuff Barriers met its specifications. All tests were verified to meet acceptance criteria. Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

5.9 Safety and Effectiveness

It has been shown in this 510(k) submission that SAMA Disposable Blood Pressure Cuff Barriers and its predicate devices have very similar indications for use, design, composition, biocompatibility, and performance.

The difference between the SAMA Disposable Blood Pressure Cuff Barriers and their predicate device do not raise any question regarding its safety and effectiveness.

SAMA Disposable Blood Pressure Cuff Barriers, as designed and manufactured, are as safe and effective as its predicate device, and therefore is substantially equivalent as its predicate device.